

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2011 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 34 – 48, 99 – 102 and 124 – 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,311,838) in view of Smith et al. (US 6,402,724) and further in view of Greco (US 5,312,385).

With reference to claims 31, 34, 43 – 47 and 99 – 100, Johnson et al. (hereinafter “Johnson”) discloses a packaging system for medical components that includes a sterilized, recessed basin (10) configured to collect fluid during irrigation of a wound

with a cover (20) that is used to provide a seal over the kit thereby keeping the components within the kit in a sterilized state.

The difference between Johnson and claim 31 is the provision that the kit specifically includes an apertured, flexible sheet and conical splash shield.

Smith et al. (hereinafter "Smith") teaches the use of a conical splash shield having the conical shape and diameter as claimed that is used in combination with and connected to an irrigation device as set forth throughout the disclosure, see especially figures 1 – 5.

It would have been obvious to one of ordinary skill in the art to provide the kit of Johnson with the conical splash shield taught by Smith because Johnson discloses that the kit may include various types of medical devices and surgical equipment as set in the abstract. Likewise, the use of a kit is beneficial because all necessary supplies and equipment are packaged together for convenience and efficiency as taught by Johnson in col. 1, lines 15 – 19.

While Johnson does not specifically recite a basin made of biocompatible, hypoallergenic material, the examiner contends that it would have been obvious to one of ordinary skill in the art to sterilize the basin of Johnson and produce it with a biocompatible hypoallergenic material since Smith recognizes the benefit of providing a safe environment for the collection of bodily fluids (col. 1, lines 6 – 34).

Likewise, it would have been obvious to one of ordinary skill in the art to provide the device with biocompatible, hypoallergenic material in order to prevent an undesirable reaction between the patient and the product.

It is noted that Smith discloses that the conical shield may include multiple materials – both flexible and inflexible -- to produce the desired results. One sheet of flexible material layer may meet the claimed limitations.

Greco teaches an irrigation kit further including a flat, apertured, flexible sheet comprised from material from the claimed group as set forth in col. 4, lines 27 – 31. With respect to specifically providing latex, the examiner contends that Greco and Smith anticipate the use of various materials and the substitution of one type of material for another, absent a teaching of unexpected result, does not patentably distinguish the claimed invention from the prior art.

It would have been obvious to one of ordinary skill in the art to provide the kit of Johnson in view of Smith with the apertured, flexible sheet as taught by Greco because Johnson discloses that the kit may include various types of medical devices and surgical equipment as set in the abstract. Likewise, the use of a kit is beneficial because all necessary supplies and equipment are packaged together for convenience and efficiency as taught by Johnson in col. 1, lines 15 – 19. Further, Greco teaches that the use of the transparent, flexible sheet provides freedom of movement and visibility while preventing unwanted contamination as set forth in the abstract.

As to claim 35, Greco and Smith disclose a flexible sheet having a shape selected from the listed group as set forth in the figures.

The difference between Johnson in view of Smith and Greco and claims 36 and 125 is the provision that the flexible sheet has a specific thickness.

Smith discloses a flexible sheet that It is noted that Smith discloses that the conical shield may include multiple materials – both flexible and inflexible -- to produce the desired results and may also have a varying thickness as set forth in col. 3, lines 41 – 52. Greco also discloses a flexible sheet that ultimately has a thickness.

It would have been obvious to one of ordinary skill in the art to modify the thickness of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65. Likewise, Greco recognizes the use of an appropriate size as set forth in col.3, lines 35 – 40.

The difference between Johnson in view of Smith and Greco and claims 37 – 38 and 101 is the provision that the flexible sheet has a specific shape.

Smith provides the specific shape as set forth in figures 1, 3 and 5.

It would have been obvious to one of ordinary skill in the art to modify the shape as disclosed by Greco since the modification of the shape of the device already disclosed by the prior art is within the level of ordinary skill in the art. Likewise, Greco recognizes the use of an appropriate size as set forth in col.3, lines 35 – 40.

The difference between Johnson in view of Smith and Greco and claims 39, 102 and 124 is the provision that the flexible sheet has a specific length.

Smith and Greco disclose a flexible sheet that has a length as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the length of Smith and/or Greco in order to determine the most effective product since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range includes only a level of ordinary skill in the art. Likewise, both references recognize the advantage of dimension modification to produce the desired result as set forth in the rejection of claim 36.

Regarding claims 40 – 42, see col. 7, lines 39 – 59 of Smith.

With reference to claim 48, Smith discloses an irrigation kit further comprising a grommet (46) as set forth in col. 7, lines 11 – 14.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,311,838) in view of Smith et al. (US 6,402,724) and Greco (US 5,312,385) and further in view of Barbut et al. (US 5,989,281).

The difference between Johnson in view of Smith and Greco and claim 32 is the provision that the kit includes a cannula having an adhesive surface.

Barbut et al. (hereinafter “Barbut”) teaches a cannula that includes an adhesive portion as set forth in col. 24, lines 12 - 15.

It would have been obvious to one of ordinary skill in the art to modify the kit of Johnson to include a cannula with an adhesive surface because the adhesive allows necessary equipment to remain attached to the cannula without additional elements and because Johnson discloses that the kit may include various types of medical devices and surgical equipment as set in the abstract.

Claims 99 – 102 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marogil (Des 386,684) in view of Smith et al. (US 6,402,724).

As to claim 99, Marogil discloses an irrigation device including a splash shield having a proximal collar and conical body that diverges in a distal direction always from the collar toward a distal rim as set forth in the figures.

The difference between Marogil and claim 99 is the provision that the splash shield is flexible and that the irrigation device includes an irrigation shield.

Smith teaches a flexible sheet configured to adapt to any number and variety of irrigation fluid delivery devices as set forth in the abstract.

It would have been obvious to one of ordinary skill in the art to provide the splash shield of Marogil with a transparent, flexible sheet because the use of such provides additional protection from backsplash during surgical procedures as taught by Smith in col. 3, lines 9 - 15.

Likewise, it would have been obvious to one of ordinary skill in the art to make the splash shield of Marogil flexible because the a flexible splash shield allows the shield to be manipulated to be formed about the unique shape of dimension of a user as taught by Smith in col. 3, lines 26 - 35.

With respect to claim 100, Smith discloses an elastically enlargeable opening as set forth in the abstract.

The difference between Marogil in view of Smith and claim 100 is the provision that the shield includes a latex portion.

It would have been obvious to one of ordinary skill in the art to provide the device of Marogil in view of Smith with a latex portion since the substitution of one type of elastic material for another is within the level of ordinary skill in the art.

As to claim 101, Smith discloses an irrigation kit wherein the flexible sheet is has an umbrella shape as set forth in figures 1, 3 and 5.

The difference between Marogil and Smith and claim 102 is the provision that the flexible sheet has a specific length.

Smith discloses a flexible sheet that has a length as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the length of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

The difference between Marogil and Smith and claim 125 is the provision that the flexible sheet has a specific thickness.

Smith discloses a flexible sheet which has a thickness as set forth in the figures.

It would have been obvious to one of ordinary skill in the art to modify the thickness of the sheet disclosed by Smith as desired since Smith acknowledges that the sheet may take any suitable form, size, shape, dimension and/or design as set forth in col. 5, lines 57 - 65.

### ***Allowable Subject Matter***

Claims 49 and 126 – 127 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the Applicant's Remarks filed October 29, 2010 with respect to claim 49 are considered persuasive, see especially page 11, 4<sup>th</sup> paragraph to the end of page 12 with

respect to the prior art references failing to teach the combination of the specific grommet and convertible portion.

### ***Response to Arguments***

Applicant's arguments, see pages 7 – 8, filed June 30, 2011, with respect to the rejection(s) of claim(s) 31 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the same references using a different interpretation.

The applicant argues that the prior art references do not provide a conical splash shield plus an additional flexible, transparent sheet. The examiner disagrees. As now set forth, Johnson provides the recessed basin as the interior of the basin itself is recessed as well as portions of the corresponding lid which will ultimately provide a basin that is "configured to" function as claimed. Smith provides the conical splash shield that has an apertured opening that is adjustable and able to be connected to various irrigation devices as well as a wound area. Greco provides the flat, flexible, apertured sheet that is fully capable of covering the conical splash shield of Smith. The examiner has also noted in the rejection that Smith discloses the use of multiple layers of materials to form the conical splash shield which may, given its broadest reasonable interpretation, be considered as the additional, flexible sheet.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele M. Kidwell whose telephone number is (571)272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/  
Primary Examiner, Art Unit 3761